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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/739,436	12/17/2003	Anna Barlow	A03P1081	9263

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PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER

GEDEON, BRIAN T

ART UNIT	PAPER NUMBER
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3766

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/739,436

Applicant(s)

BARLOW ET AL.

Examiner

Brian T. Gedeon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 1-19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the amended claims of the garter spring being “tensionally” preloaded are not supported in the specification, and are considered new matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims, as amended, regarding the garter spring as being “tensionally” preloaded is not supported in the specification, and is considered new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Lim (US Patent no. 5,769,671).

In regard to claim 1, 10, 16 and 18, Lim discloses a medical device, with an electrical contact assembly comprising (figures 1, 2, and 4): a garter spring 22 having an inner diameter; and a garter spring retainer comprising a tubular wall receiving said garter spring, the tubular wall having an inner cylindrical surface 12 defining a retainer opening 10 adapted to receive an electrical contact of an implantable lead, said tubular wall further including an outer cylindrical surface 14 having an outer diameter larger than the inner diameter of the garter spring in the relaxed state of the spring, the garter spring being thereby preloaded when the garter spring is in place on the outer cylindrical surface of the tubular wall, the tubular wall further having at least one aperture through which a corresponding section of the garter spring projects inwardly 25a-25d into the retainer opening 10 for engaging the electrical contact of the implantable lead received therein, col 4 lines 34-39.

Further in regard to claims 16 and 18, Lim further teaches that it is well known in the art that a pacing system comprises the following elements: pulse generator (contained within an implantable housing), a lead system, and an electrical interface (i.e., a header containing terminal connectors, as well as electrodes to deliver electrical pulses to tissue), col 1 lines 14-43. Lastly, Lim shows a cylindrical receptacle with a garter spring in the central opening serving as electrical connectors for medical

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electrical leads to a pulse generator. It would be obvious to one of ordinary skill in the art at the time the invention made to fabricate a medical lead with a terminal connector compatible with the connector provided on a pulse generator housing.

In regard to claims 2-6 and 11-15, Lim describes a spring 2 with several projections, 25a-25d, of the spring 2 projecting towards the center of a cylindrical connector; the projections 25s-25d project through surface 12 which retains the spring 2 in place. Figures 2, 3, and 5 of Lim show the projections being circumferentially spaced about a tubular/cylindrical wall 12, equal in length and size, equiangularly spaced, and have at least three slots where the projections 25a-25d protrude. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made in view of Lim to use some sort of retaining element around the spring in order to prevent dislodgement of the spring when a lead connector is being extracted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4: Claims 1-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lim (US Patent no. 5,769,671) in view of Acken (US Patent no. 5,324,311).

In regard to claims 1, 10, 16, and 18, describes a contact spring 2 located within the cylindrical receptacle of an electrical connector. The contact spring 2 is secured between two cylindrical surfaces 12 and 14 of the receptacle, col 3 lines 65-68 and col 4 lines 1-4 and figure 2. Several projections 25a-25d of the spring project inwardly, beyond the respective cylindrical surface 12 towards the central axis of the receptacle, col 2 lines 23-26 and 35-40. The contact spring 2 serves to engage and secure a lead connector within the receptacle in order to ensure good electrical and mechanical contact; the projections 25a-25d of the spring 2 allow for contact to be made between the spring and a lead connectors, while surface 12 locks the spring 2 in place so as to prevent possible pull-out of the spring with the extraction of the lead, col 4 lines 34-44. Acken, in the same field of endeavor as Lim, describes an electrical connector for an implantable medical device with a garter ring contact 28; the garter ring is placed within an annular groove 26 formed within the cylindrical receptacle, see Figure 1. The garter spring 28 projects into the interior of the receptacle from the annular grove 26. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the spring member of Lim with a traditional coil spring shown in Acken to secure a lead connector.

Further in regard to claims 16 and 18, Lim further teaches that it is well known in the art that a pacing system comprises the following elements: pulse generator (contained within an implantable housing), a lead system, and an electrical interface (i.e., a header containing terminal connectors, as well as electrodes to deliver electrical pulses to tissue), col 1 lines 14-43. Lastly, Lim shows a cylindrical receptacle with a

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garter spring in the central opening serving as electrical connectors for medical electrical leads to a pulse generator. It would be obvious to one of ordinary skill in the art at the time the invention made to fabricate a medical lead with a terminal connector compatible with the connector provided on a pulse generator housing.

In regard to claims 2-6 and 11-15, Lim describes a spring 2 with several projections, 25a-25d, of the spring 2 projecting towards the center of a cylindrical connector; the projections 25s-25d project through surface 12 which retains the spring 2 in place. Figures 2, 3, and 5 of Lim show the projections being circumferentially spaced about a tubular/cylindrical wall 12, equal in length and size, equiangularly spaced, and have at least three slots where the projections 25a-25d protrude. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made in view of Lim to use some sort of retaining element around the spring in order to prevent dislodgement of the spring when a lead connector is being extracted.

5. Claims 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lim (US Patent no. 5,769,671) in view of Acken (US Patent no. 5,324,311), further in view of Kast et al. (US Patent no 6,895,276).

In regard to claims 17 and 19, Acken and Lim substantially describe the invention as claimed except for the receptacle containing a slot for receiving an electrical contact assembly, for detachably latching the connector assembly within the receptacle. Kast et al. in the same field of endeavor shows a connector receptacle, figure 12, with garter springs 148. The receptacle contains a plurality of annular channels for receiving at least one electrical contact assembly, 160₁-160₄. Annular flanges 36, 38, 76, 78, figures

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2 and 3, are located on the compatible connector that is inserted into the receptacle.

The annular flanges, 36, 38, 76, 78, engage the annular channels, 160₁-160₄.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to a make receptacle connector assembly with channels or grooves to engage the annular flanges electrical contact assembly insert can be mechanically secured within the receptacle.

Response to Arguments

6. Applicant's arguments filed 6 February 2007 have been fully considered but they are not persuasive. Examiner feels that the applied references disclose the structure as claimed.

7. Applicant relies on the word "tensionally" to describe the preloading of the garter spring in order to differentiate it from the prior art, which the Applicant pointed out to be "compressively" preloaded. The Examiner respectfully disagrees. The laws of physics dictate that for every action there exists an equal and opposite reaction; therefore the garter spring in the instant application is compressively preloaded as well, which is opposite to an expansive tension forces applied to the spring. The garter spring of the instant application is exerting a compressive force on the outer cylindrical surface of the tubular wall, and uses compressive preloading forces to secure an electrical connector inserted into the electrical contact assembly. Therefore the application is not differentiated from the prior art.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Stutz, Jr. (US Patent no. 5,076,270) depicts a method for making electrical connections in an implantable pacemaker.
- Truex et al. (US Patent no. 4,934,366) describes a feedthrough connector for implantable medical device using a garter spring.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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PRIMARY EXAMINER